CLINUVEL

ASX ANNOUNCEMENT

Melbourne, Australia, 24 April 2026

ASX: CUV | **Börse Frankfurt**: UR9 | **ADR Level I**: CLVLY

CLINUVEL receives final EMA scientific advice for pivotal Phase III vitiligo study

"Totality of evidence" approach to evaluate SCENESSE®

EXECUTIVE SUMMARY

- final European scientific advice received for pivotal Phase III vitiligo study
- EMA emphasised its "totality of evidence" approach
- central photographic review and validated disease assessment tools agreed
- CUV107 to compare SCENESSE® with adjunct NB-UVB vs NB-UVB monotherapy
- CUV107 study (n=300) to commence in 2H 2026

CLINUVEL PHARMACEUTICALS LTD today announced that the European Medicines Agency (EMA) has provided final scientific advice on the design of the planned pivotal Phase III CUV107 study and anticipated evaluation of evidence of CLINUVEL's drug SCENESSE® (afamelanotide) as a systemic vitiligo treatment.

EMA's Scientific Advice[1]

Following over 12 months of interaction, two formal submissions and a Discussion Meeting with the EMA's Scientific Advice Working Party (SAWP), the Committee for Medicinal Products for Human Use (CHMP), has issued Scientific Advice on CLINUVEL's program evaluating SCENESSE® as a systemic therapy for adults and adolescents with non-segmental vitiligo.

The EMA proposed to evaluate the efficacy of SCENESSE® in vitiligo based on a regulatory approach of "totality of evidence", with T-VASI50[2] the primary endpoint while patient reported outcomes and clinical data from the other vitiligo studies with SCENESSE® will be evaluated for final analyses of efficacy and safety.

Given the importance of patients' perceptions of visible change in pigmentation, the EMA emphasised that the assessment by vitiligo patients themselves would play an important role in the final evaluation when vitiligo data from CUV107 and previous studies would be submitted for marketing authorisation.

In particular, photographic evidence of change from baseline (CFB) will be used to assess primary and secondary endpoints, T-VASI50[2] and F-VASI75[3], with an array of other related secondary objectives. In total, five patient and physician surveys are integrated in the study to record Patient Reported Outcomes.

The EMA advised that patients of darker skin colours (Fitzpatrick IV-V-VI) would benefit from systemic treatment first, since the visibility of disease – due to the contrast between unaffected skin and vitiligo lesions – is most pronounced in these patient groups.

Commentary

"The dialogue took one year but eventually resulted in a one-off position taken by the Agency, who are now fully across the SCENESSE® program and possible expected outcomes in vitiligo," said Dr Emilie Rodenburger, CLINUVEL's Director, Global Clinical Affairs.

"A major step forward was the request by the SAWP to access photographic changes of vitiligo patients receiving treatment, which demonstrated visual improvement in pigmentation.

"The Discussion Meetings provided three take aways: the patient population of darker skin complexion will be the first to benefit from a systemic treatment, the design of the study and, significantly, the 'totality of evidence' approach which will be taken during final evaluation of evidence submitted to the EMA. We can only be appreciative of the extensive work the Agency has done to get across our program," Dr Rodenburger concluded.

[1]Scientific Advice provided by the EMA is non-binding but good practice and documented in the final EPAR (European Public Assessment Report) issued at the conclusion of a marketing authorisation evaluation. The EMA provides opportunities during the clinical development program for drug developers to seek formal guidance, with a focus on advising on expected standards to establish pre-clinical and clinical safety and efficacy.

[2]CLINUVEL will use T-VASI50 - the proportion of patients who achieve 50% or more repigmentation of the total body excluding hands and feet during the study – as the primary endpoint; this will be indicative but not determinative for efficacy.

[3] F-VASI75 - the proportion of patients who achieve 75% or more repigmentation of head and neck (excluding lips) and excluding hands and feet during the study – is being used as a secondary endpoint; this will be indicative but not determinative for efficacy.

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About vitiligo

Vitiligo is believed to be a multifactorial disorder with immune components in some cases resulting in progressive loss of pigment (melanin) of the skin and associated with a severe impact on quality of life. It affects an estimated 0.5%-2% of the general population, with no approved therapies for patients with extensive depigmentation (affecting >10% of total body surface area).

About CLINUVEL PHARMACEUTICALS LIMITED

CLINUVEL (ASX: CUV; ADR LEVEL I: CLVLY; Börse Frankfurt: UR9) is a global specialty pharmaceutical group focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as healthcare solutions for specialised populations. As pioneers in photomedicine and the family of melanocortin peptides, CLINUVEL's research and development has led to innovative treatments for patient populations with a clinical need for systemic photoprotection, assisted DNA repair, repigmentation and acute or life-threatening conditions who lack alternatives.

CLINUVEL's lead therapy, SCENESSE® (afamelanotide 16mg), is approved for commercial distribution in Europe, the USA, Israel, and Australia as the world's first systemic photoprotective drug for the prevention of phototoxicity (anaphylactoid reactions and burns) in adult patients with erythropoietic protoporphyria (EPP). Headquartered in Melbourne, Australia, CLINUVEL has operations in Europe, Singapore, and the USA. For more information, please go to https://www.clinuvel.com.

Authorised for ASX release by the Board of Directors of CLINUVEL PHARMACEUTICALS LTD.

Head of Investor Relations

Mr Malcolm Bull, CLINUVEL PHARMACEUTICALS LTD

Investor Enquiries

https://www.clinuvel.com/investors/contact-us

Forward-Looking Statements

This release contains forward-looking statements, which reflect the current beliefs and expectations of CLINUVEL's management. All statements other than statements of historical or current facts made in this document are forward-looking. We identify forward-looking statements in this document by using words or phrases such as "anticipate," "believe," "consider," "continue," "could," "estimate," "expect," "foresee," "intend," "likely," "may," "objective," "potential," "plan," "predict," "project," "seek," "should," "will" and similar words or phrases and their negatives. Forward-looking statements reflect our current expectations and are inherently uncertain. Actual outcomes or results could differ materially for a variety of reasons. Statements may involve a number of known and unknown risks that could cause our future results, performance, or achievements to differ significantly from those expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialise pharmaceutical products; the COVID-19 pandemic and/or other world, regional or national events affecting the supply chain for a protracted period of time, including our ability to develop, manufacture, market and sell biopharmaceutical and PhotoCosmetic products; competition for our products, especially SCENESSE® (afamelanotide 16mg), CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed and characterised by us as PhotoCosmetics; our ability to achieve expected safety and efficacy results in a timely manner through our innovative R&D efforts; the effectiveness of our patents and other protections for innovative

products, particularly in view of national and regional variations in patent laws; our potential exposure to product liability claims to the extent not covered by insurance; increased government scrutiny in either Australia, the U.S., Europe, the UK, Israel, China, Japan, and/or LATAM regions of our agreements with third parties and suppliers; our exposure to currency fluctuations and restrictions as well as credit risks; the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement; that the Company may incur unexpected delays in the outsourced manufacturing of SCENESSE®, CYACÊLLE, PRÉNUMBRA®, NEURACTHEL® or products developed as PhotoCosmetics which may lead to the Company being unable to launch, supply or serve its commercial markets, special access programs and/or clinical trial programs; any failures to comply with any government payment system (i.e. Medicare, Medicaid, and U.S. Department of Veteran's Affairs) reporting and payment obligations; uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology, cosmetic and consumer based products; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; our ability to retain or attract key personnel and managerial talent; the impact of broader change within the pharmaceutical industry, cosmetic industry and related industries; potential changes to tax liabilities or legislation; environmental risks; and other factors that have been discussed in our 2025 Annual Report. Forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation, outside of those required under applicable laws or relevant listing rules of the Australian Securities Exchange, to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. More information on preliminary and uncertain forecasts and estimates is available on request, whereby it is stated that past performance is not an indicator of future performance.

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